

General

Guideline Title

Deep venous thrombosis and thromboembolism in patients with cervical spinal cord injuries. In: Guidelines for the management of acute cervical spine and spinal cord injuries.

Bibliographic Source(s)

Dhall SS, Hadley MN, Aarabi B, Gelb DE, Hurlbert RJ, Rozzelle CJ, Ryken TC, Theodore N, Walters BC. Deep venous thrombosis and thromboembolism in patients with cervical spinal cord injuries. In: Guidelines for the management of acute cervical spine and spinal cord injuries. Neurosurgery. 2013 Mar;72(Suppl 2):244-54. [57 references] PubMed

Guideline Status

This is the current release of the guideline.

Recommendations

Major Recommendations

The rating schemes used for the strength of the evidence (Class I-III) and the levels of recommendations (Level I-III) are defined at the end of the "Major Recommendations" field.

Recommendations

Prophylaxis

Level I

- Prophylactic treatment of venous thromboembolism (VTE) in patients with severe motor deficits due to spinal cord injury (SCI) is recommended.
- The use of low molecular weight heparins (LMWHs), rotating beds, or a combination of modalities is recommended as a prophylactic treatment strategy.
- Low dose heparin in combination with pneumatic compression stockings or electrical stimulation is recommended as a prophylactic treatment strategy.

Level II

- Low dose heparin therapy alone is not recommended as a prophylactic treatment strategy.
- Oral anticoagulation alone is not recommended as a prophylactic treatment strategy.

- Early administration of VTE prophylaxis (within 72 hours) is recommended.
- A 3-month duration of prophylactic treatment for deep vein thrombosis (DVT) and pulmonary embolism (PE) is recommended.

Level III

• Vena cava filters are not recommended as a routine prophylactic measure, but are recommended for select patients who fail anticoagulation or who are not candidates for anticoagulation and/or mechanical devices.

Diagnosis

Level III

 Duplex Doppler ultrasound, impedance plethysmography, venous occlusion plethysmography, venography, and the clinical examination are recommended for use as diagnostic tests for DVT in the spinal cord-injured population.

Summary

Thromboembolic disease is a common occurrence in patients who have sustained a cervical spinal cord injury and is associated with significant morbidity. Class I medical evidence exists demonstrating the efficacy of several means of prophylaxis for the prevention of thromboembolic events. Therefore, patients with SCI should be treated with a regimen aimed at VTE prophylaxis.

Although low dose heparin therapy has been reported to be effective as prophylaxis for thromboembolism in several Class III studies, other Class II, Class II, and Class III medical evidence indicates that better alternatives than low dose heparin therapy exist. These alternatives include the use of LMWH, adjusted dose heparin, or anticoagulation in conjunction with rotating beds, pneumatic compression devices or electrical stimulation. Oral anticoagulation alone does not appear to be as effective as these other measures used for prophylaxis.

There appears to be a DVT prophylaxis benefit to early anticoagulation in acute SCI patients. Class II medical evidence supports beginning mechanical and chemical prophylaxis upon admission after SCI and holding chemical prophylaxis 1 day prior to and 1 day following surgical intervention.

The incidence of thromboembolic events appears to decrease over time and the prolonged use of anticoagulant therapy is associated with a definite incidence of bleeding complications. There are multiple reports of the beneficial effects of the prophylaxis therapy for 6 to 12 weeks following SCI. Class II medical evidence indicates that the majority of thromboembolic events occur in the first 3 months following acute SCI and very few occur thereafter. For these reasons, it is recommended that prophylactic therapy be discontinued after 3 months unless the patient is at high risk for a future VTE event (previous thromboembolic events, obesity, advanced age). It is reasonable to discontinue therapy earlier in patients with retained lower extremity motor function after SCI, as the incidence of thromboembolic events in these patients is substantially lower than among those patients with motor complete injuries.

Although the guidelines author group concluded that caval filters appeared to be efficacious for the prevention of PE in SCI patients in the 2002 guideline on this topic, more recent medical evidence suggests that prophylactic filters may be more morbid than initially believed. Caval filters still have a role for SCI patients who have suffered thromboembolic events despite anticoagulation, and for SCI patients with contraindications to anticoagulation and/or the use of pneumatic compression devices.

There are several methods available for the diagnosis of DVT. Venography has long been considered the best test, but is invasive, not applicable to all patients, and is associated with intrinsic morbidity. Duplex Doppler ultrasound, impedance plethysmography, venous occlusion plethysmography and the clinical examination have been reported to have sensitivities of approximately 90% and are noninvasive. It is recommended that these noninvasive tests be used for the diagnosis of DVT in SCI patients and that venography to diagnose DVT be reserved for the rare situation when clinical suspicion is high and the results of ultrasound or plethysmography testing are negative.

Definitions:

Rating Scheme for the Strength of the Evidence: Modified North American Spine Society Schema to Conform to Neurosurgical Criteria as Previously Published and for Ease of Understanding and Implementation: Levels of Evidence for Primary Research Question^a

Class	Therapeutic Studies: Investigating the Results of Treatment	Diagnostic Studies: Investigating a Diagnostic Test	Clinical Assessment: Studies of Reliability and Validity of Observations, Including Clinical Examination, Imaging Results, and Classifications
I	High-quality randomized controlled	Testing of previously developed	Evidence provided by 1 or more well-designed clinical

Class	trial with statistically significant. The appendix Studies: Investigating the difference or no statistically significant Results of Treatment difference but narrow confidence intervals	diagnostic criteria on Diagnostic Studies: Investigating consecutive patients (with a Diagnostic Test universally applied reference "gold" standard)	ctudies in which interobserver and intraobserver
	Systematic review ^b of Class I randomized controlled trials (and study results were homogeneous ^c)	Systematic review ^b of Class I studies	
П	Lesser-quality randomized controlled trial (e.g., <80% follow-up, no blinding, or improper randomization)	Development of diagnostic criteria on consecutive patients (with universally applied reference "gold" standard)	Evidence provided by 1 or more well-designed clinical studies in which interobserver and intraobserver reliability is represented by a Ä, statistic of 0.40–0.60 or an intraclass correlation coefficient of 0.50–0.70
	Prospective ^d comparative study ^e	Systematic review ^b of Class II studies	
	Systematic review ^b of Class II studies or Class I studies with inconsistent results	Study of nonconsecutive patients; without consistently applied reference "gold" standard	
	Case-control study ^g	Systematic review ^b of Class III studies	
	Retrospective ^f comparative study ^e	Case-control study	
	Systematic review ^b of Class II studies		
Ш	Case series ^h	Poor reference standard	Evidence provided by 1 or more well-designed clinical studies in which interobserver and intraobserver reliability is represented by a Ä, statistic of <0.40 or an intraclass correlation coefficient of <0.50
	Expert opinion	Expert opinion	

^aA complete assessment of quality of individual studies requires critical appraisal of all aspects of the study design.

ePatients treated 1 way (e.g., halo vest orthosis) compared with a group of patients treated in another way (e.g., internal fixation) at the same institution.

^gPatients identified for the study on the basis of their outcome, called "cases" (e.g., failed fusion), are compared with those who did not have outcome, called "controls" (e.g., successful fusion).

^hPatients treated 1 way with no comparison group of patients treated in another way.

Levels of Recommendation

Level	Generally accepted principles for patient management, which reflect a high degree of clinical certainty (usually this requires Class I
I	evidence which directly addresses the clinical questions or overwhelming Class II evidence when circumstances preclude randomized

^bA combination of results from 2 or more prior studies.

^cStudies provided consistent results.

^dStudy was started before the first patient enrolled.

^fThe study was started after the first patient was enrolled.

	clinical trials)
Level II	Recommendations for patient management which reflect moderate clinical certainty (usually this requires Class II evidence or a strong consensus of Class III evidence)
Level III	Other strategies for patient management for which the clinical utility is uncertain (inconclusive or conflicting evidence or opinion)

Clinical Algorithm(s)

None provided

Scope

Disease/Condition(s)

Deep venous thrombosis and thromboembolism following acute cervical spinal cord injury

Guideline Category

Diagnosis

Management

Prevention

Treatment

Clinical Specialty

Hematology

Neurological Surgery

Neurology

Orthopedic Surgery

Radiology

Intended Users

Advanced Practice Nurses

Hospitals

Nurses

Physician Assistants

Physicians

Guideline Objective(s)

To update, evaluate, and rank the literature on the methods of prevention, identification, and treatment of venous thromboembolism (VTE) complications in patients following acute cervical spinal cord injury (SCI) published since 2002

Target Population

Patients who have sustained cervical spinal cord injuries (SCIs) at risk for deep venous thrombosis (DVT) and thromboembolism

Interventions and Practices Considered

Diagnosis

- 1. Duplex Doppler ultrasound
- 2. Impedance plethysmography
- 3. Venous occlusion plethysmography
- 4. Venography
- 5. Clinical examination

Prevention/Treatment

- 1. Low-molecular-weight heparins
- 2. Rotating beds
- 3. Low-dose heparin combined with pneumatic compression stockings or electrical stimulation
- 4. Early administration of venous thromboembolism (VTE) prophylaxis (within 72 hours)
- 5. Three-month duration of prophylactic therapy
- 6. Vena cava filters (for select patients only)
- 7. Combination of modalities

Note: Low-dose heparin alone and oral anticoagulation alone were considered but not recommended for prophylaxis.

Major Outcomes Considered

- Risk of deep vein thrombosis (DVT)
- Incidence of DVT and pulmonary embolism (PE)
- Sensitivity and specificity of diagnostic tests for DVT
- Adverse effects of prophylactic interventions
- Effectiveness of prophylactic interventions

Methodology

Methods Used to Collect/Select the Evidence

Hand-searches of Published Literature (Primary Sources)

Hand-searches of Published Literature (Secondary Sources)

Searches of Electronic Databases

Description of Methods Used to Collect/Select the Evidence

Search Criteria

A National Library of Medicine (PubMed) computerized literature search from 1966 through 2011 was performed using Medical Subject

Headings in combination with "spinal cord injury": "deep venous thrombosis," "pulmonary embolism," and "thromboembolism." The search was limited to human studies reported in the English language. This resulted in 599 citations. Duplicate references, reviews, letters, and tangential reports were discarded. The bibliographies of these citations were analyzed for additional potential contributions. Finally, the author group found 45 citations describing the diagnosis, prophylaxis or treatment of thromboembolic disease in adult spinal cord injured patients make up the basis for this guideline. Supporting references included 4 evidence-based reviews on venous thromboembolism (VTE) prophylaxis and treatment in a variety of patient populations. Finally, several series dealing with VTE in general trauma patients with results germane to a discussion of spinal cord injured patients are included in the bibliography as supporting documents.

Number of Source Documents

Forty-five citations describing the diagnosis, prophylaxis or treatment of thromboembolic disease in adult spinal cord injured patients make up the basis for this guideline and are summarized in Evidentiary Table format (see the table in the original guideline document).

Methods Used to Assess the Quality and Strength of the Evidence

Weighting According to a Rating Scheme (Scheme Given)

Rating Scheme for the Strength of the Evidence

Rating Scheme for the Strength of the Evidence: Modified North American Spine Society Schema to Conform to Neurosurgical Criteria as Previously Published and for Ease of Understanding and Implementation: Levels of Evidence for Primary Research Question^a

Class	Therapeutic Studies: Investigating the Results of Treatment	Diagnostic Studies: Investigating a Diagnostic Test	Clinical Assessment: Studies of Reliability and Validity of Observations, Including Clinical Examination, Imaging Results, and Classifications
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	Systematic review ^b of Class I randomized controlled trials (and study results were homogeneous ^c)	Systematic review ^b of Class I studies	
П	Lesser-quality randomized controlled trial (e.g., <80% follow-up, no blinding, or improper randomization)	Development of diagnostic criteria on consecutive patients (with universally applied reference "gold" standard)	Evidence provided by 1 or more well-designed clinical studies in which interobserver and intraobserver reliability is represented by a Ä, statistic of 0.40–0.60 or an intraclass correlation coefficient of 0.50–0.70
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	Retrospective ^f comparative study ^e	Case-control study	
	Systematic review ^b of Class II studies		

Glass	Therapeutich Studies: Investigating the Case series Results of Treatment	Diagnostic Studies: Investigating Poor reference standard a Diagnostic Test	Clinical Assessment: Studies of Reliability and Validity Evidence provided by 1 or more well-designed clinical of Observations, Including Clinical Examination, studies in which interobserver and intraobserver Imaging Results, and Classifications, reliability is represented by a A, statistic of <0.40 or an intraclass correlation coefficient of <0.50
	Expert opinion	Expert opinion	

^aA complete assessment of quality of individual studies requires critical appraisal of all aspects of the study design.

^ePatients treated 1 way (e.g., halo vest orthosis) compared with a group of patients treated in another way (e.g., internal fixation) at the same institution.

^gPatients identified for the study on the basis of their outcome, called "cases" (e.g., failed fusion), are compared with those who did not have outcome, called "controls" (e.g., successful fusion).

Methods Used to Analyze the Evidence

Systematic Review with Evidence Tables

Description of the Methods Used to Analyze the Evidence

Selected articles were carefully reviewed by the authors. An evidentiary table was created (refer to the table in the original guideline document) that reflected the strengths and weaknesses of each article.

On occasion, the assessed quality of the study design was so contentious and the conclusions so uncertain that the guideline authors assigned a lower medical evidence classification than might have been expected without such a detailed review. In every way, adherence to the Institute of Medicine's criteria for searching, assembling, evaluating, and weighing the available medical evidence and linking it to the strength of the recommendations presented in this document was carried out.

Articles that did not achieve immediate consensus among the author group were discussed extensively until a consensus was reached. Very few contributions required extensive discussion. Most articles were easily designated as containing Class I, II, or III medical evidence using the criteria set forth by the author group at the initiation of the literature evaluation process (see the "Rating Scheme for the Strength of the Evidence" field).

Methods Used to Formulate the Recommendations

Expert Consensus

Description of Methods Used to Formulate the Recommendations

The current author group was selected for its expertise in spinal surgery (both neurosurgical and orthopedic), neurotrauma, clinical epidemiology, and, in several cases, prior experience with guideline development. The topics chosen for inclusion in this iteration of these guidelines are contemporary and pertinent to the assessment, evaluation, care, and treatment of patients with acute cervical spine and/or spinal cord injuries.

^bA combination of results from 2 or more prior studies.

^cStudies provided consistent results.

^dStudy was started before the first patient enrolled.

^fThe study was started after the first patient was enrolled.

^hPatients treated 1 way with no comparison group of patients treated in another way.

Rating Scheme for the Strength of the Recommendations

Levels of Recommendation

Level I	Generally accepted principles for patient management, which reflect a high degree of clinical certainty (usually this requires Class I evidence which directly addresses the clinical questions or overwhelming Class II evidence when circumstances preclude randomized clinical trials)
Level	Recommendations for patient management which reflect moderate clinical certainty (usually this requires Class II evidence or a strong consensus of Class III evidence)
Level	Other strategies for patient management for which the clinical utility is uncertain (inconclusive or conflicting evidence or opinion)

Cost Analysis

The guideline developers reviewed a published cost analysis.

Method of Guideline Validation

Not stated

Description of Method of Guideline Validation

Not applicable

Evidence Supporting the Recommendations

Type of Evidence Supporting the Recommendations

The type of supporting evidence is identified and graded for each recommendation (see the "Major Recommendations" field).

Benefits/Harms of Implementing the Guideline Recommendations

Potential Benefits

Accurate diagnosis and prevention of deep venous thrombosis (DVT) and thromboembolism

Potential Harms

- Prolonged prophylactic anticoagulation therapy is not without risk, and is associated with bleeding complications.
- The placement of inferior vena cava (IVC) filters is not without complications. Several authors have described distal migration, intraperitoneal erosion, and symptomatic IVC occlusion in patients with spinal cord injuries (SCIs) treated with IVC filters. One group of researchers has hypothesized that quadriplegic patients are at higher risk for complications from IVC filter placement due to loss of abdominal muscle tone, as well as their requisite use of the "quad cough" maneuver.
- Venography has been considered the best test for diagnosis of deep vein thrombosis (DVT), but is too inaccurate, is not possible in all
 patients, is invasive, and expensive. A 10% incidence of adverse effects from venography including post-venographic phlebitis and allergic
 reactions has been reported.

Qualifying Statements

Qualifying Statements

- Medical evidence-based guidelines are not meant to be restrictive or to limit a clinician's practice. They chronicle multiple successful treatment options (for example) and stratify the more successful and the less successful strategies based on scientific merit. They are not absolute, "must be followed" rules. This process may identify the most valid and reliable imaging strategy for a given injury, for example, but because of regional or institutional resources, or patient co-morbidity, that particular imaging strategy may not be possible for a patient with that injury. Alternative acceptable imaging options may be more practical or applicable in this hypothetical circumstance.
- Guidelines documents are not tools to be used by external agencies to measure or control the care provided by clinicians. They are not medical-legal instruments or a "set of certainties" that must be followed in the assessment or treatment of the individual pathology in the individual patients we treat. While a powerful and comprehensive resource tool, guidelines and the recommendations contained therein do not necessarily represent "the answer" for the medical and surgical dilemmas faced with many patients.

Implementation of the Guideline

Description of Implementation Strategy

An implementation strategy was not provided.

Implementation Tools

Mobile Device Resources

For information about availability, see the Availability of Companion Documents and Patient Resources fields below.

Institute of Medicine (IOM) National Healthcare Quality Report Categories

IOM Care Need

Getting Better

Staying Healthy

IOM Domain

Effectiveness

Identifying Information and Availability

Bibliographic Source(s)

Dhall SS, Hadley MN, Aarabi B, Gelb DE, Hurlbert RJ, Rozzelle CJ, Ryken TC, Theodore N, Walters BC. Deep venous thrombosis and thromboembolism in patients with cervical spinal cord injuries. In: Guidelines for the management of acute cervical spine and spinal cord injuries. Neurosurgery. 2013 Mar;72(Suppl 2):244-54. [57 references] PubMed

Adaptation

Not applicable: The guideline was not adapted from another source.

Date Released

2013 Mar

Guideline Developer(s)

American Association of Neurological Surgeons - Medical Specialty Society

Congress of Neurological Surgeons - Professional Association

Source(s) of Funding

Congress of Neurological Surgeons

Guideline Committee

Guidelines Author Group of the Joint Section of Disorders of the Spine and Peripheral Nerves of the American Association of Neurological Surgeons and the Congress of Neurological Surgeons

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Financial Disclosures/Conflicts of Interest

The authors have no personal financial or institutional interest in any of the drugs, materials, or devices described in this guideline.

Guideline Status

This is the current release of the guideline.

Guideline Availability

Electronic copies: Available in Portable Document Format (PDF) and EPUB for eBook devices from the Neurosurgery Web site

Availability of Companion Documents

The following are available:

•	Foreword. Guidelines for the management of acute cervical spine and spinal cord injuries. Neurosurgery 2013;72(3):1. Electronic copies:
	Available in Portable Document Format (PDF) from the Neurosurgery Web site
•	Commentary. Guidelines for the management of acute cervical spine and spinal cord injuries. Neurosurgery 2013;72(3):2-3. Electronic
	copies: Available in PDF from the Neurosurgery Web site
•	Introduction to the guidelines for the management of acute cervical spine and spinal cord injuries. Neurosurgery 2013;72(3):5-16. Electronic
	copies: Available in PDF from the Neurosurgery Web site
•	Methodology of the guidelines for management of acute cervical spine and spinal cord injuries. Neurosurgery 2013;72(3):17-21. Electronic
	copies: Available in PDF from the Neurosurgery Web site

Patient Resources

None available

NGC Status

This NGC summary was completed by ECRI Institute on July 9, 2013. The information was verified by the guideline developer on October 3, 2013. This summary was updated by ECRI Institute on March 10, 2014 following the U.S. Food and Drug Administration advisory on Low Molecular Weight Heparins.

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